

Quantification of the amount of capsid protein present in a sample of an individual may be used in determining the prognosis of an infected individual.

The present invention relates to antibodies which specifically bind to capsid protein from WNV or other viruses including *Flavivirus* or *Pestivirus*. The antibodies are preferably monoclonal antibodies. The antibodies are preferably raised against capsid protein made in human cells, CHO cells, insect cells or yeast cells.

The present invention relates to kits for identifying individuals exposed to WNV or other viruses including *Flavivirus* or *Pestivirus* comprising a first container which contains antibodies which specifically bind to capsid protein from WNV or other viruses including *Flavivirus* or *Pestivirus* and a second container which contains capsid protein as a positive control. The antibodies are preferably monoclonal antibodies. The antibodies are preferably raised against capsid protein made in human cells, CHO cells, insect cells or yeast cells. The capsid protein is preferably made in human cells, CHO cells, insect cells or yeast cells. The kits may be adapted for quantifying of the amount of capsid protein present in a sample of an individual.

Another aspect of the invention is a diagnostic test in which the presence and/or amount of anti-capsid protein from WNV or other viruses including *Flavivirus* or *Pestivirus* antibodies in a test sample is determined. In the diagnostic method of the present invention, the presence of anti-capsid protein antibodies in a test sample from an individual is an indicator of infection.

The present invention relates to methods of identifying individuals exposed to WNV or other viruses including *Flavivirus* or *Pestivirus* by detecting presence of antibodies against capsid protein from WNV or other viruses including *Flavivirus* or *Pestivirus* in sample using capsid protein. The capsid protein is preferably produced in human cells, CHO cells, insect cells or yeast cells. Quantification of the amount of anti-capsid protein antibodies present in a sample of an individual may be used in determining the prognosis of an infected individual.

The present invention relates to isolated capsid protein. The capsid protein is preferably produced in human cells, CHO cells, insect cells or yeast cells.

The present invention relates to kits for identifying individuals exposed to WNV or other viruses including *Flavivirus* or *Pestivirus* comprising a first container which contains antibodies which specifically bind to capsid protein from WNV or other viruses including *Flavivirus* or *Pestivirus* and a second container which contains capsid protein. The capsid protein is preferably produced in human cells, CHO cells, insect cells or yeast cells. The antibodies are preferably raised against capsid made in human cells, CHO cells, insect cells or yeast cells. The kits may

be adapted for quantifying the amount of anti-capsid protein antibodies present in a sample of an individual. Such information may be used in determining the prognosis of an infected individual.

Kits for the detection of capsid protein from WNV or other viruses including *Flavivirus* or *Pestivirus* and anti-capsid protein from WNV or other viruses including *Flavivirus* or *Pestivirus* antibodies are useful for research as well as diagnostic and prognostic purposes.

The means to detect the presence of a protein or an antibody in a test sample are routine and one having ordinary skill in the art can detect the presence or absence of a protein or an antibody using well known methods. One well known method of detecting the presence of a protein or an antibody is in a binding assay. One having ordinary skill in the art can readily appreciate the multitude of ways to practice a binding assay to detect the presence of a protein or an antibody. For example, antibodies are useful for immunoassays which detect or quantitate a specific protein. Antigens are useful for immunoassays which detect or quantitate a specific antibody. Some immunoassays comprise allowing proteins in the test sample to bind a solid phase support or to antibodies fixed to a solid phase. Detectable antibodies are then added which selectively binding to either the protein of interest or the uncomplexed antibody. Detection of the detectable antibody indicates the presence of the protein of interest if the detectable antibody is specific for the protein or the absence of the protein of interest if the detectable antibody is specific for uncomplexed antibody. Some immunoassays comprise allowing antibodies in the test sample to bind to an antigen that is fixed to a solid phase support and detecting the antigen/antibody complex using a detectable antibody which binds to either the antibody of interest or the antigen. Various immunoassay procedures are described in *Immunoassays for the 80's*, A. Voller *et al.*, eds., University Park Press, Baltimore (1981), which is incorporated herein by reference.

Simple binding assays may be performed in which a solid phase support is contacted with the test sample. Any proteins present in the test sample bind the solid phase support and can be detected by a specific, detectable antibody preparation. Such a technique is the essence of the dot blot, Western blot and other such similar assays. The presence of specific antibodies in a test sample may also be detected in a similar manner. A target protein, to which the specific antibody binds, is contacted with the test sample and the subsequent binding to antibodies, if present in the test sample, is analyzed by a variety of methods known to those skilled in the art.

Any antibodies present in the test sample bind the solid phase support and can be detected by detectable antigen or a specific, detectable antibody preparation.

Other immunoassays may be more complicated but actually provide excellent results. Typical and preferred immunometric assays include "forward" assays for the detection of a protein in which a first anti-protein antibody bound to a solid phase support is contacted with the test sample. After a suitable incubation period, the solid phase support is washed to remove unbound protein. A second, distinct anti-protein antibody is then added which is specific for a portion of the specific protein not recognized by the first antibody. The second antibody is preferably detectable. After a second incubation period to permit the detectable antibody to complex with the specific protein bound to the solid phase support through the first antibody, the solid phase support is washed a second time to remove the unbound detectable antibody. Alternatively, the second antibody may not be detectable. In this case, a third detectable antibody, which binds the second antibody is added to the system. This type of "forward sandwich" assay may be a simple yes/no assay to determine whether binding has occurred or may be made quantitative by comparing the amount of detectable antibody with that obtained in a control. Such "two-site" or "sandwich" assays are described by Wide, *Radioimmune Assay Method*, Kirkham, ed., E. & S. Livingstone, Edinburgh (1970) pp. 199-206, which is incorporated herein by reference.

The "forward" assay may also be adapted for the detection of antibodies that may be present in a test sample, henceforth referred to as "sample antibodies." The specific target protein to which the sample antibodies bind is bound to the solid phase support and contacted with the test sample. After a suitable incubation period, the solid phase support is washed to remove unbound sample antibodies. A first antibody that binds to the Fc portion of the sample antibodies is added. This first antibody is preferably detectable. Alternative, in the case where the first antibody is not detectable, a second detectable antibody which binds the first antibody must be used to detect the binding. After a second incubation period to permit the detectable antibody to complex with the sample antibody bound to the target protein/solid phase support, the solid phase support is washed a second time to remove the unbound detectable antibody. This type of "forward sandwich" assay may also be a simple yes/no assay to determine whether binding has occurred or may be made quantitative by comparing the measure of detectable antibody with that obtained in a control.